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March 2, 2012

SUBMITTED ELECTRONICALLY

Docket No. FSIS 2005-0016
United States Department of Agriculture
FSIS, OPPD, RIMD
Docket Room
Patriots Plaza 3
1400 Independence Ave. SW
Mailstop 3782, 8–163A
Washington, DC 20250-3700

Re: Docket No. FSIS 2005-0016; Prior Label Approval System: Generic Label Approval

Dear Sir or Madam:

The National Chicken Council (NCC) appreciates the opportunity to comment on the Food Safety and Inspection Service's (FSIS's) proposed rule entitled "Prior Label Approval System: Generic Label Approval," published in the *Federal Register* on December 5, 2011. NCC represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States. NCC's members routinely develop poultry product labels and would be directly affected by a final rule on generic labeling.

NCC and our members are committed to ensuring food labeling is truthful, accurate, and informative. We recognize the important role FSIS label review plays in this process, but we also experience first-hand the costs to both industry and the agency of a label review system not capable of distinguishing between simple, routine label submissions and those raising important public health or policy issues. NCC supports expanding generic labeling to streamline the label review process and appreciates the opportunity to provide these comments on the agency's proposal.

I. The Proposed Changes Explained in the Preamble Offer Much-Needed Reform to the Label Approval Process

NCC and our members support the agency's efforts to reduce waste and inefficiencies by streamlining the label approval process. The current system imposes significant costs on the agency and industry, consuming resources that could be better spent developing innovative products and enhancing food safety. The agency each year reviews and routinely approves thousands of clear-cut labels presenting no risk to public health and raising no special policy concerns. Despite the routine nature of these approvals, the agency expends a significant amount of its limited resources on these reviews, and NCC's members must bear the costs of label

submissions and of production delays associated with label approvals. The increasingly lengthy review process and its sometimes unpredictable nature are especially burdensome on our members, as they require submitting labels for review increasingly earlier in the production cycle or risking production interruptions because of delays in obtaining approval. These routinely approved labels present no public health risks or difficult public policy issues, rendering individual review unnecessary and wasteful. Eliminating the label-review burden for these labels would free agency resources for increased efforts in areas more critical to food safety and consumer welfare and would enable NCC's members to devote more resources to product innovation and food safety.

The agency's proposal to expand generic approval to the basic label elements and to statements or claims "defined in FSIS's regulations or policy guidance," 1/ while reserving formal label review for only those special statements or claims "more likely to present significant policy issues that have health or economic significance" 2/ represents an appropriate and realistic solution to the pressing label review problem. Doing so would eliminate the need to review label elements based on rules industry can readily understand and meet while ensuring the agency retains direct review authority over developing policy areas and labeling aspects raising significant public health issues. The agency can also devote some of its newly freed resources to developing further labeling policies to guide industry.

NCC supports efforts to streamline label approval, but the proposed rule requires additional refinement to bring about the efficiencies envisioned by the agency.

II. The Definition of "Special Statements or Claims" Should Be Clarified to Reflect the Preamble

FSIS should revise the proposed regulatory text to ensure "special statements or claims" are defined as envisioned in the preamble. As noted, the preamble explains the agency would not require submission and review for "statements on labels that are defined in FSIS's regulations or policy guidance." 3/ The agency lists allergen statements, which are explained only in guidance, as an example of label feature that would be subject to generic approval under the proposal. 4/ NCC and its members strongly support the agency's decision that claims and statements defined in "policy guidance" should be subject to generic approval.

The proposed regulatory text, though, defines special statements or claims as those "that are not defined in the Federal meat and poultry products inspection regulations," omitting all reference to agency policy guidance. 5/ This proposed text is inconsistent with both the intent expressed in the preamble and the specific results contemplated by the agency. Under the proposed text, for example, allergen statements would not be subject to generic approval because they are not defined in FSIS regulations, directly contradicting the agency's desired result and frustrating the

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1/ 76 Fed. Reg. 75809, 75814 (Dec. 5, 2011).
2/ *Id.* at 75813.
3/ *Id.* at 75814.
4/ *Id.*
5/ *Id.* at 75824 (proposed § 412.1(e)).

agency's efforts to modernize the label approval system. It seems an odd result to require further agency rulemaking to codify developed agency policies to effectuate the changes envisioned in the preamble. FSIS should revise proposed section 412.1(e) to define "special statements and claims" as those "that are not defined in the Federal meat and poultry products inspection regulations or in FSIS written policy guidance."

III. Reform Is Furthered by Placing Additional Claims Under Generic Approval

To fully modernize the label approval process consistent with the agency's proposal, additional statements or claims should be brought under generic approval, and generic approval should be extended to encompass certain approvals related to temporary approvals.

- Generic Extension of Temporary Approvals. NCC's members' experiences indicate the agency routinely approves initial requests for extensions of temporary approvals beyond the initial 180-day temporary approval window. These extensions become necessary when an establishment is unable to exhaust its label stock during the initial window. Given the routine nature of these approvals and the fact that FSIS has already approved the initial temporary approval, the agency should generically approve the first 180-day extension of a temporary approval.

- Generic Approval Based on a Prior Temporary Approval. When the agency issues a temporary approval, it is effectively telling the establishment what problems the agency identifies with the existing label and how those problems should be fixed. Submitting the corrected sketch approval becomes redundant in light of the agency's prior review and issuance of the temporary approval. Generic approval should extend to final labels that correct the mistake identified in temporarily approved label.

- Generic Approval of Temporary Labels for Minor Inaccuracies Presenting No Public Health or Consumer Welfare Risk. To significantly reduce the volume of temporary label approval requests—and the additional costs associated with short-notice emergency situations—the agency should authorize generic approval for temporary labels with minor technical violations that post not public health or consumer welfare risks. Examples of such approvals include changes requiring a minor reordering of the order of predominance of ingredients in the ingredient statement, the substitution of a similar ingredient that does not materially change the nutrition profile or introduce an allergen not declared on the label (e.g., substituting one type of vegetable oil for another), and other comparable changes to the other basic, required label elements.

IV. Effective Enforcement Requires Clear Procedures and an Understanding of Appropriate Roles

The streamlining and modernization envisioned by the agency will be realized only if FSIS develops clear procedures for monitoring and inspecting generically approved labels and clearly specifies how alleged violations should be addressed. NCC recognizes that the increased emphasis on proper documentation and recordkeeping by establishments necessarily relies on the ability of the agency to access and review generic approval files. But without clearly defined

roles and procedures, label approval risks becoming decentralized and inconsistent, noncompliant labels going undetected, and enforcement growing inconsistent, undermining the proposed rule's intended efficiencies.

The agency should develop a clear policy explaining how inspectors are to inspect generic label approvals and how inspectors should respond to suspected violations. It would be appropriate for inspectors to review an establishment's generic approval files, to compare product formulations against generically approved labels, and to ensure labels affixed to products reflect the labels on file. In addition to detailing these inspection procedures, the agency should make clear that it is not appropriate to tag and retain product or otherwise stop the production line absent a clear and imminent risk to public health. Nor are noncompliance records (NRs) an appropriate vehicle to raise issues about an establishment's generically approved labeling.

Moreover, inspectors should be provided and trained to use a clear channel of communications upward through the FSIS organization. Such a mechanism would ensure that FSIS's Labeling and Policy Development Division (LPDD) will ultimately be able to provide the agency's position on a questioned label, fostering both efficiency and fairness. Further, inspectors must be trained to differentiate between situations in which they suspect a label was not eligible for generic approval (*e.g.*, the label includes a special statement or claim requiring FSIS review) and situations in which they suspect the label was eligible for generic approval but the establishment may have misapplied a regulation (*e.g.*, making a nutrient content claim that does not comply with the applicable regulation). In the latter situation, especially when the establishment believes it has appropriately used the claim, it will be essential that the inspector receive guidance from LPDD before taking action against the product. In neither case would it be appropriate to take immediate action absent the rare situation that presents a clear risk to publish health.

To assure all involved that clear procedures will be implemented, FSIS should commit through the rulemaking process to developing this framework. Providing clear procedures, proper direction, and appropriate training will be crucial not only for ensuring accurate labeling, but also for realizing the efficiencies that can be gained by streamlining the label approval process.

Conclusion

NCC supports efforts to reform the FSIS label approval process by expanding generic approval. The label approval process is in dire need of reform, and the principle announced in the preamble—reserving agency resources for reviewing only labels presenting difficult public health or policy issues—would create a workable, realistic framework for this reform. Clarity as to requirements and appropriate roles will be crucial to enacting meaningful reform, though, and NCC urges the agency to incorporate these recommendations into a final rule on generic label approval.

Please do not hesitate to contact us if we may be of assistance. Thank you for your consideration.

Respectfully submitted,

Michael J. Brown
President